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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 09/639,207 | 08/14/2000 | Parsa Kazemi-Esfarjani | 06618-686001 | 9459 |
| 20985 | 7590 | 12/09/2003 | EXAMINER | |
| FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081 | | | SULLIVAN, DANIEL M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |
| DATE MAILED: 12/09/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/639,207

Applicant(s)

KAZEMI-ESFARJANI ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,29-32,34,37-40 and 42-79 is/are pending in the application.
- 4a) Of the above claim(s) 47-49 and 51-79 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26,29-32,34,37-40 and 50 is/are allowed.
- 6) ☒ Claim(s) 42 and 43 is/are rejected.
- 7) ☐ Claim(s) 44-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is a reply to the "AMENDMENT" of 15 September 2003 (hereinafter, 15 September Paper) filed in response to the Non-Final Office Action mailed 19 June 2003 (hereinafter, 19 June Office Action). Claims 26, 29-35, 37-40, 42-46 and 50 were considered in the 19 June Office Action. Claims 33 and 35 were canceled and claims 26, 34, 37, 39 and 50 were amended in the 15 September paper. Claims 26, 29-32, 34, 37-40 and 42-79 are pending, claims 47-49 and 51-79 are withdrawn from consideration. Claims 26, 29-32, 34, 37-40, 42-46 and 50 are presently under consideration.

Response to Amendment

Claim Rejections - 35 USC § 112

Claims 42 and 43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and herein below in the response to arguments.

Claim Rejections - 35 USC § 103

Rejection of claims 26, 29-34, 37-40 and 50 under 35 U.S.C. 103(a) as being unpatentable over Warrick *et al.* as evidenced by Paulson is withdrawn.

Rejection of claims 26 and 42 under 35 U.S.C. 103(a) as being unpatentable over Warrick *et al.* as evidenced by Paulson and in view of Rørth is withdrawn.

Response to Arguments

Claims 42 and 43 were rejected as lacking adequate written description for a genus of *D. melanogaster* comprising a marker located adjacent to or inserted into any gene whose expression or activity increases or decreases polyglutamine toxicity in the animal. In response to the rejection of record, Applicant urges, because claim 26 has not been rejected as lacking adequate written description, claims 42 and 43, which depend from claim 26 and incorporate additional elements, must also satisfy the written description requirement. This argument has been fully considered but is not deemed persuasive because it is the additional elements recited in claims 42 and 43 that are not adequately described. Claim 26 has not been rejected because the transgenic *D. melanogaster* of the claim is not limited to comprising a marker located adjacent to or inserted into any gene whose expression or activity increases or decreases polyglutamine toxicity in the animal. Because the *D. melanogaster* of claim 26 is not limited to comprising a marker gene adjacent to or inserted into a gene having the recited activity, the description of claim 26 need not demonstrate possession of the genus at issue in claims 42 and 43.

With regard to claim 43, Applicant further argues that “J domain” containing molecules are both structurally and functionally recognized in the art and therefore demonstrate that the inventors had possession of the claimed invention. This argument is not found persuasive because there is no demonstrated nexus between the “J domain” structure and the recited function of increases or decreases polyglutamine toxicity. That is, the skilled artisan would not recognize the “J domain” structure as a relevant identifying characteristic of the genus of genes capable of increasing or decreasing polyglutamine toxicity.

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Applicant's arguments have been fully considered but are not deemed persuasive individually or as a whole. Therefore claims 42 and 43 stand rejected under 35 U.S.C. §112, first paragraph.

Allowable Subject Matter

Claims 26, 29-32, 34, 37-40 and 50 are allowed.

Claims 44-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Please note: Art Unit 1636 will be moving to the new USPTO facilities on 14 January 2004. After that date, Examiner Sullivan can be reached at 571-272-0779 and Examiner Yucel can be reached at 571-272-0781.

DMS

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER